Intervention fidelity in post-intensive care follow-up consultations at ten sites in the RAPIT-trial

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TITLE PAGE

Title of the manuscript

Intervention fidelity in post-intensive care follow-up consultations at ten sites in the RAPIT-trial: a mixed-methods evaluation

Short running title

Intervention fidelity in cross-site implementation of follow-up consultations among nurses

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Involved in drafting the manuscript or revising it critically for important intellectual content;	JFJ, DO, MB, DC, JR, IE
Given final approval of the version to be published. Each author should have participated sufficiently in the work to take public responsibility for appropriate portions of the content;	JFJ, DO, MB, DC, JR, IE
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Conflicts of interest statement

No conflicts of interest have been declared by the authors.

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Keywords

Ambulatory Care Facilities, Aftercare, Complex interventions, Empowerment, Fidelity, Mixed Methods, Implementation, Intensive Care Unit, Nursing, Rehabilitation

ABSTRACT

Aim: The aim of the study was to evaluate intervention fidelity of nurses' delivery of the RAPIT recovery program for post intensive care patients.

Background: Interventions addressing patient problems after intensive care lack description of the process of delivery and the evidence of their effectiveness. This is needed to understand how these interventions work.

Design: Multistage intervention framework in a mixed-methods design. Intervention fidelity strategies were assessed for intervention design, training, delivery, receipt and enactment with quantitative and qualitative methods inspired by the Medical Research Council and the National Institutes of Health Fidelity Framework.

Methods: Data collection was embedded in a multicenter randomized controlled trial to explore intervention fidelity of a recovery program (December 2012 - February 2017). Ten Danish intensive care units participated in the RAPIT-trial including 386 patients and 27 nurses. Quantitative data covered training and delivery. Qualitative data explored design, quality of delivery, receipt and enactment seen from nurses' and patients' perspectives. Data were analyzed statistically and by systematic deductive-inductive thematic analysis.

Findings: A framework for participatory enactment of a complex intervention was developed and demonstrated delivery with high consistent fidelity across sites. Low delivery doses and variations were related to the program, patient, provider nurses and context.

Conclusion: Our study provides insight into the process of intervention fidelity of a nurse-led post intensive care recovery program and potentially enables professionals to understand key factors in cross-site implementation. Although we demonstrate consistent delivery and variations suggest that some patients may benefit more than others.

Key words: critical care, mixed method design, outpatient clinics, rehabilitation, empowerment, research in practice, nursing

SUMMARY STATEMENT

Why is this research needed?

- Follow-up clinics have emerged in an ad hoc manner with heterogeneous delivery and uncertain evidence of delivery.
- For study replication, study generalizability and for reduced random and unintentional variability, intervention fidelity is needed to fully understand how the results were obtained.
- Knowledge of the level of delivery, patient and healthcare provider receipt and enactment and the impact of the implementation process in randomized controlled trials, provides an understanding of the influence of contextual factors on the results.

What this paper adds

- The study is instrumental in demonstrating how mixed methods can help researchers to improve consistent delivery and identify issues that potentially affect the results of a complex intervention.
- The study highlights training, monitoring and feedback as a means to improve consistent delivery and adherence to the protocol of a complex intervention.

- The study shows how mixed methods add to a more comprehensive understanding of the process and insights into participants' experiences in a complex intervention trial of an ICU recovery program.

Implications for practice

- The study potentially helps professionals to understand factors of importance for consistent delivery of an intervention across sites.
- The study potentially informs nurses wishing to evaluate complex interventions in similar settings.

INTRODUCTION

Intensive care unit (ICU) survivors commonly suffer physical, psychological and cognitive impairment (Needham et al. 2012, Aitken and Marshall 2015) leading to lower quality of life and prolonged recovery (Oeyen et al. 2010). Consequently, follow-up programs for patients with critical illness have emerged to help patients recover. The National Institute for Health and Care Excellence (NICE) guidelines recommend individualized rehabilitation to help the recovering patients after intensive care (National Institute for and Clinical 2009), physical as well as 'non-physical' domains. In Denmark, conventional rehabilitation has focused on physical training rather than psychological support. But the delivery of psychological rehabilitation initiatives is uncertain and the evidence of their effectiveness is limited (Jensen et al. 2015, Ullman et al. 2014). To our knowledge, intervention fidelity has not previously been evaluated in trials of psychological rehabilitation. Therefore, more knowledge is needed to understand factors influencing interventional outcomes in this patient group.

Background

Worldwide million patients require treatment in intensive care unit (ICU) and survival is expected to rise due to the aging population and advances in critical care medicine (Vincent and Creteur 2015). Critical illness can lead to the development of new or worsen impairments, termed as "Post Intensive Care Syndrome" (PICS). PICS includes physical, psychological and cognitive impairments persisting for months or years after ICU (Granja et al. 2012, Angus et al. 2003). It is estimated to affect two out of three ICU survivors, of whom 13-20% are severely impaired in their daily living (Griffiths and Jones 2002). As more patients survive critical illness with impairments (Angus et al. 2003), post-ICU programs are emerging to promote recovery (Griffiths et al. 2006). NICE guidelines recommend individualized rehabilitation to help patients recover after ICU (National Institute for and Clinical 2009). In Denmark, psychological recovery in ICU follow-up interventions has been an adjunct to conventional rehabilitation that covers a physical discharge rehabilitation plan, if ordered by a physician (Ministry of Social Affairs 2009). Interventions constructed to aid psychological recovery post-ICU, such as diaries and follow-up consultations, are examples of complex interventions that have been tested and implemented with heterogeneous delivery and limited evidence of their effectiveness (Jonasdottir et al. 2016, Ullman et al. 2014).

There is increasing evidence of the importance of evaluating intervention fidelity in complex interventions. Intervention fidelity is needed to fully understand how results were obtained, for study replication, study generalizability and for reduced random and unintentional variability (Bellg et al. 2004, Spillane et al. 2007, Borrelli 2011). Implementing complex interventions requires treatment fidelity assessment referring to methodological practices used to establish the extent to which an intervention is delivered as planned (Craig et al. 2013), as it combines adherence to protocol with skillfulness in delivery (Song et al. 2010). The Treatment Fidelity Workgroup of the National Institutes of Health (NIH) recommends assessing treatment fidelity strategies for intervention design, training, delivery, receipt and enactment with quantitative and qualitative methods (Bellg et al. 2004, Borrelli 2011). To avoid confusion regarding the type of participants, receipt covers how patients

actually received the intervention and the nurses' ability to use their skills learned in the treatment. Enactment refers to patients and nurses' ability to implement treatment skills in a real-life setting.

This study is set within the context of the Recovery and Aftercare in Post Intensive care Therapy patient (RAPIT) trial (Jensen et al. 2016). The one-year trial aimed to evaluate the effectiveness of a program empowering patients as a means to improve psychological recovery post-ICU compared with standard care. The intervention and trial's timeframe is described in Appendix 1. The intervention was delivered by specially trained ICU-nurses. Standard care included light sedation, early mobilization, written information for visitors and ICU discharge without follow-up. Physical training was initiated in the ICU and physical rehabilitation was offered to all patients (Jensen et al. 2016).

The effectiveness of this complex intervention was evaluated in a multicenter randomized controlled trial (RCT) at ten Danish ICUs (Jensen et al. 2016). We found no difference in health-related quality of life, sense of coherence, anxiety, depression and posttraumatic stress disorder at 12 months after ICU discharge (Jensen et al. 2016). But an exploratory analysis revealed a significant difference in severe anxiety at 3 months favoring the intervention (Jensen et al. 2016). Existing trials of psychological post-ICU rehabilitation lack evaluation of intervention fidelity limiting their generalizability and acceptability (Jonasdottir et al. 2016, Jensen et al. 2015, Lasiter et al. 2016). A theory-driven evaluation of intervention fidelity assessment was needed. The goal is to describe fidelity, quality of implementation and identify contextual influences on outcomes (Craig et al. 2013). A fidelity framework inspired by NIH was used to assess intervention fidelity from the perspective of nurses and patients (Craig et al. 2013, Borrelli 2011), Fig. 1.

METHODS

Aim

The aim of the study was to evaluate intervention fidelity using a mixed-methods approach.

The specific objectives of the study were to:

1. Evaluate the intervention fidelity of study design, provider training, delivery, receipt and enactment where receipt and enactment was evaluated seen from the perspective of nurses and patients on the program
2. Explore rationales behind the achieved fidelity level.

Design

Intervention fidelity was explored using a mixed-methods design underpinning by a multi-stage intervention framework (Creswell and Plano Clark 2011), with the qualitative component had priority in terms of explanatory power i.e. QUAL-quant. We selected these complementary methods to obtain a more comprehensive understanding of the process of intervention fidelity and to explore underlying explanations for the summative assessment of nurses.

Participants

Ten Danish ICUs participated in the RAPIT-trial. The ICUs were identified through a Danish network of ICU nurses (Egerod 2011) and ICUs were reduced to nine as a result of unit amalgamation. The participants were 386 post-ICU patients and 27 ICU nurses.

The quantitative component included all patients enrolled in the RAPIT-trial and this is described in details in a previous paper (Jensen et al. 2016)**.** Inclusion criteria for patients were post-ICU Danish-speaking adults, who had received ≥48h of mechanically ventilation and enrollment was based on a sample size calculation (Jensen et al. 2016). The nurse manager at each unit identified and selected participating nurses based on their in-depth knowledge of the nursing staff and by using three criteria: (I) motivation, (II) ICU-certification and (III) ≥ two years of ICU-experience. Provider nurses (PNs) conducted consultations (N=19) and functioned as primary investigators at each site. Other participating nurses assisted (N=8) by photographing and identify eligible patients for potential inclusion. A random sample of 88 of 366 nurse-led consultations provided contextual information for assessing fidelity of delivery during the trial.

The qualitative component was a strategically selected sub-group of consultations (N=12) and exit-interviews (exploring nurses' experience of the study) (N=14) ensuring maximum variation of patients and nurses in each site. We selected nurses according to ICU-experience and patients according to age, gender, diagnosis, length of mechanical ventilation and ICU-stay (Patton 1987).

Data collection

Quantitative and qualitative data were collected during and after the RAPIT-trial in 2012-2017. The trial started at December 2012 with a pilot phase of four months to train nurses. Quantitative data included design, training and delivery of the intervention, Fig. 2. Data on design were based on reviewing the literature (Jensen et al. 2014). Provider Nurse training was assessed by a multiple-choice test (N=17) and their activity rate on a protected blog. Delivery was assessed by patient case report forms (N=386), direct observation (N=10) and audited consultations (N=88). Data were then rated on a priori checklist (by JFJ) where each item was rated as 'yes/present' or 'no/absent'. The multiple-choice test was constructed for the study and assessed knowledge after four one-day training workshops for PNs (N=19) including questions about inclusion procedure, data collection, communication and use of reflection sheets. To assess delivery toward salient components of the intervention we compared audio-recorded consultations to a checklist covering theory, content and use of prerequisites, Appendix 1. Every three-six month we randomly selected consultations at each site for audits. Nurses received feedback to improve knowledge and maintain consistent delivery.

Three qualitative data sources reflected design, the quality of delivery, receipt and enactment before, during and after the trial. They consisted of focus group discussions (FGDs) (N=3), transcribed interviews data generated by audio-recordings of consultations (N=12, 36 consultations) and exit semi-structured telephone interviews (N=14). FGD were integrated at workshops, where the first author was moderator and the co-investigators were observers. We planned workshops based on nurses' feedback regrading ongoing theoretical and hands-on learning with involvement from experts, appendix 2. FGD explored design and delivery. The interview guide in first FGD covered different models of follow-up (Egerod et al. 2013). Interview guide in the second FGD covered 'What was a

good consultation'. The interview guide at last FGD covered 'consistent delivery of core component'. We used transcribed interviews to explore receipt and enactment, appendix 3. Interviews of patient consultations followed the content and structure of consultations, appendix 1. All nurses involved in the RAPIT-trial were invited to exit-interviews to discuss allocation, components, experiences and recommendations. The first question was: 'What was your experiences of the RAPIT-trial?'. The mean duration of interviews was 39 min. (range 23-55).

Ethical considerations

Approval was obtained for the study from management teams in each participating ICU by a signed agreement of cooperation. PN were informed in writing and verbally and each nurse gave written consent to participate in exit-interview. Patients and relatives in the RAPIT-trial gave written informed consent prior to participation. The RAPIT-trial was registered at www.clinicaltrials.gov (no. NCT01721239) and approved by the National Committee on Health Research ethics (no. H-1-2012-FSP-60) and the Danish Data Protection Agency (Umbrella notification no. 2007-58-0015, project no. 01863 HIH-2012-011).

Data analysis

Quantitative data were analyzed using descriptive statistics including frequencies, percentages and means. The cutoff score of the multiple-choice test was set at a mean score of 75% correct answers to ensure a minimum of knowledge. The content of consultations was reflected in a checklist with the fulfillment of >85%, which should count for high adherence (Borrelli 2011). Unsuccessful delivery was defined as absent on the checklist and resulted in verbal feedback to PNs and an audit of the following consultation until our criteria of success at 85% were achieved.

Qualitative data were analyzed using deductive-inductive thematic analysis (Braun V 2006). Interviews were transcribed verbatim and an external interviewer conducted nurses' exit-interview. The first phase was developing a theoretical deductive analytical basis of the conceptual framework in

the intervention and second phase was to supplement the analysis with an inductive approach based on themes identified by 36 transcribed consultations and nurses' exit-interviews (N=14) (Braun V 2006). The analysis was supported by NVivo version 10 (NVivo qualitative data analysis software; QSR International Pty Ltd. Version 10 2014).

We adopted a multistage interventional model to collect and analyze data (Creswell and Plano Clark 2011). We expanded the evaluation of intervention fidelity with several qualitative data sources and embedded data at the interpretation level using triangulation methods and presented through narrative in a weaving approach (Fetters et al. 2013).

Rigour

Reflexivity is the process of recognizing constructs that influence the research process (Guba and Lincoln 2005). Investigator triangulation was used in the analytical process, confirmability was achieved by methodological triangulation, credibility was obtained by using several methods to study intervention fidelity, dependability by providing participant quotes and transparency was enhanced by describing the processes of sampling, data collection and analysis (Malterud 2001).

FINDINGS

Participant characteristics

We included 27 female nurses with a mean of 14 years (range 4-30) of ICU-experience and a mean age of 49 (range 32-59). Fifteen nurses held master's degrees; 9 PNs and 6 assisting nurses. Ten study nurses dropped out due to maternity leave (N=2), or career moves (N=8) where four out of eight started jobs within areas of research (N=4). Exit-interviews were conducted with 12 PNs and two assisting nurses aged 38-59 with 7-30 years of ICU experience. Patients (N=12) participating in consultations were eight males and four females, with a mean age of 61 (range 19-84), mean duration of mechanical ventilation 346 hours (range 49-1018) and mean ICU length of stay 18 days (range 4-

44). Nurses from nine ICUs were represented and patients from the ten ICUs are referred to as P1 to P12.

Treatment design and dose

A focus group discussion involved ICU nurses with experience in follow-up programs (N=21), as an expert panel to discuss designs of ICU follow-up in general. This resulted in including patient photographs as they could be delivered consistently (Akerman et al. 2013) and we obtained consensus on a standardized intervention guideline based on the literature review (Jensen et al. 2014). To reduce contamination the control group referred directly to first author (JFJ). The dose was assessed by photographs, information pamphlets and consultation that was regarded as satisfactory, Fig. 3.

Patient photographs were included in both groups because they were taken before randomization. Among 386 patients 1917 pictures were taken, evenly distributed in the two groups. In each group photographs were missing in 18 patients for pragmatic reasons. Each ICU provided a mean of five photographs per patient (range 3-7). Most patients wished to keep their photographs (N=131), but some declined fearing that the pictures might be upsetting (N=5).

Information pamphlets were received by all 190 patients in the intervention group and none in the control group.

Nurse-led consultations were part of the intervention. The intervention group received 376 consultations and three patients were placed in the intervention group by mistake. We noted some irregularities: five patients in the control group had physician-led consultations, seven patients (N=2 interventions and N=5 controls) had received <48h of ventilatory support after validating the observed time on the ventilator. These patients were excluded from the trial's per-protocol analysis. During the first consultation, 112 patients visited the ICU and 12 declined. No adverse events were reported. The dropout excluding deaths (28% vs. 22% in intervention vs. control) was high in this population.

Training providers

The training plan was driven by the protocol. It started with a four-day theoretical and practical workshop supplemented with a project protected blog and on-site observation and feedback to ensure PN skills acquisition. Training workshops were directed towards discussions, roleplays and group assignments to obtain a shared understanding and support consistent delivery across sites. Nurses were unable to attend all workshops due to clinical responsibilities. To overcome this gap, we provided a protected blog to ensure that each site had unlimited online support with instruction videos and study protocol materials (JF et al. 2012). On-site training focused on local implementation strategies including feedback of the recruitment procedure and the patient's first consultation (N=10).

The mean score of the multiple-choice test on PN knowledge was 81% with two missing (N=17), appendix 4. It showed that some PNs needed more training in "Screening for ICU-delirium" and "Reflection sheets". The PNs obtained overall satisfactory knowledge above the cut-off at 75%.

During each workshop 7-9 of the trial sites were represented. Two nurses from each ICU participated at most workshops, usually the PN and in the beginning the managing and clinical nurses also attended. The last workshop included presentations at each site (N=7 sites/83 participants). Attendance rate was regarded as satisfactory, appendix 2.

The protected blog recorded peak activity during recruitment and training followed by a downward curve by 2275, 1212 and 348 views and 107, 59 and 23 visitors, respectively. The blog was rated as satisfactory.

The piloting phase was conducted at four sites (N=27 patients). The set time-points for consultations were experienced as too rigid and flexibility was added, Fig. 1. We encouraged each ICU to recruit at least two PNs to accommodate for dropouts. The pilot test and training resulted in ongoing workshops throughout the trial as means to maintain nurses' skills. After these adjustments were made, we regarded the intervention as feasible.

Delivery of Treatment

Actual delivery was assessed quantitatively by audits (N=88) and the quality of delivery was evaluated by focus groups (N=2). Selected quotes are presented in Table 1. The audits revealed that an empathic, respectful, kind and acknowledging atmosphere in the consultations characterized the situation, Fig 3. Nurses shared responsibility by giving patients options, creating clarity and understanding. Three audits were repeated as nurses provided too much advice and excessive advice reduced shared responsibility. The structure of consultations was generally delivered as intended. Unsuccessful delivery was categorized as follows: unstructured (N=1, CI), lack of patient reflection (N=2, CII and CIII) and reflection sheets refused (N=2, CIII). Audits revealed that photographs were used and PNs realized the importance of photographs for patients. Audits demonstrated that PNs used communication techniques as intended with high conformity except 'consultations summary' and 'pauses'. The audits demonstrated that the intervention was carried out as planned with satisfactory and consistent delivery according to the checklist showing 93%, 91% and 96% fulfillment of criteria respectively, Fig. 2.

Two focus groups primarily discussed quality of delivery. Nurses experienced some variations in CII and CIII related to patients' readiness and obtaining a natural flow in consultations. Nurses had different experiences of readiness that reflected the heterogeneity of patients. Readiness was related to the timing of consultations, patients' level of reflection and lack of nonverbal cues of communication by telephone. The natural flow of consultations was challenged by a simultaneous focus on questions and responses, resulting in PNs changing the order of questions or rephrasing questions. In summary, assessment of the delivered intervention was satisfactory; PNs demonstrated sufficient adherence to protocol and skillfulness in delivery.

Receipt

The actual receipt of intervention as well as the nurses' use of skills learned during the trial were recorded (N=12, 36 consultations). Selected quotations are presented in Table 1. All participants treated each other as equal partners creating a trusting, nonjudgmental atmosphere. It was necessary for patients to approach the subject gradually, initiated by small talk, before revealing what had troubled them during the time span from hospitalization to first consultation, CI. The interaction was in CII and CIII added humor as an icebreaker and a sign of an alignment between two people, which created a more personal connection based on a shared understanding.

The easiest way to start a conversation in CI was to ask the patients how they were doing. This provided the patients with an active role as narrator. Initiating CI with a (confrontational) question of what the patient recalled from ICU was ineffective and provided an incoherent story. Nurses started CII and CIII in a small-talk fashion by asking patients what happened between consultations. Patients perceived this as a genuine interest in the person behind the illness, providing a deeper and more intimate consultation saving time by avoiding irrelevant issues.

The main component in CI was photographs followed by an ICU-visit and the provision of an information pamphlet. The photographs gave patients the opportunity to experience the lost time and for nurses to explain the environment. The ICU-visit included meeting the staff if requested by the patient. The pamphlet was of more use to the relatives than patients. Nurses used the reflection sheets as the interview guide. The patients did not have an intuitive understanding of the reflection sheets during CII, because their insights were still new and unexpected. At CIII, the reflection sheets were used more expertly and patients had a chance to more readily come to terms with their experiences. All nurses used the learned communication techniques as intended. Mirroring gave a more detailed description of patient experiences and was often used as a part of active listening. Value-clarifying responses were used to discuss alternative ways of managing everyday life. The expanded reply was the most commonly used response followed by active listening and mirroring. Nurses summarized consultations and used pauses at CIII more than at CI and CII. Nurses ended consultations by showing gratitude for the patient's participation in the trial.

Enactment

Enactment of skills to identify contextual factors was assessed during the exit-interview (N=14) exploring PNs experiences and patient responses to the intervention by coding consultations (N=12, 36 consultations). Selected quotations are presented in Table 2.

PNs experiences: Main theme: Prepare nurses for research

The central theme that emerged, structuring the meaning of experiences of the interventions' delivery seen from nurses' perspective was 'prepare nurses for research'. Prepare nurses for research was obtained through four themes: individual patient benefit from intervention, research beside daily practice, learning process linked to practice and peers support and prerequisites for implementation, Fig 4.

Theme: Individual patient benefit from intervention

Nurses grasped the consequences of critical illness during allocation procedures. The mortality rate was high and PNs regarded patient survival as life with sequelae. The RCT design created some conflicts for nurses until they fully understood it. The most troublesome for nurses was the random allocation as they compared it with 'winning the lottery'. Nurses felt that patients were disappointed if were in the control group. Nurses realized that some patients were unsuitable for the intervention due to poor health, had little to say, or only attended consultations to please the nurses. Nurses felt that pictures should be considered carefully and reflect decent pictures because they were dependent upon retrospective consent. Nurses realized that consultations had the potential to increase patient's safety, but all three consultations were not always necessary.

Theme: Research beside daily practice

Nurses experienced that research was an addition to clinical practice and increased their workload. Research required more documentation and patients were difficult to track when discharged early. Research was described as systematic detective work.

Theme: Learning process linked to practice and peer support

Learning was a process of 'learning by doing' supported by peers. Nurses enacted skills while receiving feedback from peers, patients and investigators. They viewed research as educational, but found it difficult at first. The intervention prepared them to talk about long-term effect of critical illness. The communication skills acquired were used and also transferred to other contexts, such as training staff members and other patient conversations. Networking with peers at workshop created a shared interest that generated energy, ownership and kept up the spirit over time because nurses gained new knowledge and insights by reflecting on experiences across sites. Nurses experienced that ownership depended on the degree of involvement in the trial and was reinforced by attending workshops.

Theme: Prerequisites for implementation

Some factors were facilitators or barriers to implementation. Nurses felt that leadership and management support was essential for allocation of resources to deliver the intervention. Selecting providers based on previous experience with project management were important competencies to secure progress over time. Research required work based on mutual trust, patience and responsibility including an open-minded attitude to adapt changes. It became important for nurses to inform colleagues regularly about trial progression to legitimize their absence at bedside and ask for practical help. It was portrayed as a new culture for nurses to do clinical research.

Patient responses

Patient response to the intervention was positive and empowering. Some patients expressed a need to talk about experiences to move on at CI. Some patients found CII helpful by providing clarity and back-up during recovery. During CIII, some patients found follow-up beneficial, Table 2. Patients appreciated the chance to reflect and tell their story. Some patients spontaneously stated that the intervention had increased their self-knowledge and reduced their insecurity by maintaining contact to the hospital. Patients experienced a release by telling their story to an empathic listener who knew what they had gone through.

DISCUSSION

The aim of this study was to evaluate and explore intervention fidelity at the ten sites included in the RAPIT-trial. We have presented a framework for assessing intervention fidelity of a complex intervention based on five domains (design, training, delivery, receipt and enactment) (Bellg et al. 2004, Borrelli 2011). The intervention content was delivered overall with high fidelity across sites over time, but in terms of intervention doses received, some of allocated patients (less than a third) did not receive the three consultations mainly due to serious illness. This could result in incomplete outcome data and the failure of the intervention. We tried to resolve these issues by estimating power, balance low coverage between conditions, conducting missing data analysis (Higgins et al. 2011), which results in less biased estimates compared with not addressing missing data at all (Groenwold et al. 2012). High dropout rate is a common challenge encountered in other interventions aiming at ICU survivors, such as physical rehabilitation (Connolly et al. 2015). Future studies might consider electronic data entry and consultations that are even more flexible because this could have improved response rate and delivery.

One of the key findings was that qualitative data expanded the quantitative results. This adds to a more comprehensive understanding of the process and insights into participants' experiences in a complex intervention trial of an ICU recovery program. By exploring participants' receipt and

enactment, we found different possible explanations for the achieved level of intervention fidelity (e.g., the individualization of the program, learning experiences and conducting research in clinical practice). Intervention fidelity was not without variations in nurses' ability to deliver and these variations were related to program, patient, providers and context. Existing literature has shown these elements may have an impact on the fidelity of interventions' delivery (Carroll et al. 2007).

This study suggested variations due to preferences and conditions of patients. Patients responded differently to the opening and the reflection sheet was challenging for few patients in terms of the intuitively understanding and the willingness discussing the reflection sheet. This might be a sign of cognitive or mental impairments after critical illness (Needham et al. 2012). A recent study has indicated that three out of four ICU survivors develop new neurocognitive impairments and one of the risk factors is mechanical ventilation (Turon et al. 2018). Avoidance might be a symptom of PTSD recognized among post-ICU patients (Davydow et al. 2008). Consequently, some consultations were classified as 'not delivered as intended'. The intervention cannot be delivered in the exact same way with all patients because patient responses differ (Song et al. 2010). Overall, patients, who completed the program, were positive and highly valued the intervention. This is in accordance with existing evaluations of nurse-led intensive care programs and process evaluations of patient and carer experiences of a complex rehabilitation program after ICU (Glimelius et al. 2011, Prinjha et al. 2009, Samuelson and Corrigan 2009, Ramsay et al. 2016).

On the provider-nurses level, we developed a plan to achieve the necessary competencies and ability to execute the plan within a multimodal framework of training, workshops and internet learning. Research on fidelity of complex interventions confirms the need for continuous supervision and feedback to obtain fidelity based on shared understanding across the study team (Mertens et al. 2015, Reynolds et al. 2014). Inspired by participatory research we used feedback, defining goals and reinforcement as factors to facilitate learning (Rushmer and Davies 2004). Workshops might have a positive impact on learning that created a positive collaborative relationship with peers based on a common language. This might be the explanation for the nurses' high level of consistent delivery across sites that increased nurses' sense of ownership and interest for academic thinking supported by

leaders and managing nurses. However, ten qualified motivated nurses dropped out in the study period. Perhaps, it influenced the progression of the study as 124 patients never were approached due to fast discharge and it might seem demotivating on the remaining nurses even though we over recruited nurses to accommodate dropout. As such, motivation may not be the best indicator to enroll nurses. Two elements that probably sustained nurses were workshops and feedback.

The context can be considered as a key moderator of intervention fidelity (Carroll et al. 2007). The context in this study can be summarized in the main theme 'prepare nurses for research', because the setting, collaborative relationship, required skills of the nurse and the condition of the patient had an impact on intervention fidelity of delivery. Prepare nurses for research was a step in the direction of changing the culture in clinical nursing toward a nursing research culture (Berthelsen and Holge-Hazelton 2017). By exploring nurses' perspectives of enactment, we found examples of how complex nursing research in real-life settings is practiced.

Methodological considerations

The strengths of this study were the mixed data collection and integrating the qualitative component in a real-life setting to understand contextual factors during the intervention that might affect the outcome (Craig et al. 2013). A particular strength of our evaluation was addressing intervention fidelity based on a framework recommended by others (Rixon et al. 2016, Lambert et al. 2017).

There are some limitations. We tried to assess fidelity in the control group (Bellg et al. 2004), but we might have missed other contextual issues, such as relatives taking photographs. The nurse manager at each unit selected nurses and it is possible that these nurses were chosen for reasons of retention rather than motivation. The assessment tools, such as the multiple-choice test and checklist was constructed for this study and have not been validated. We chose clinical study nurses for implementation, which has been proven effective by others (Balas et al. 2012, Ng and Curley 2012). The study was conducted in a multicenter partnership in real-life setting, which enhanced the generalizability to similar studies investigating intervention fidelity of complex interventions.

CONCLUSION

We demonstrate that the intervention was delivered as planned and that intervention fidelity can be performed in parallel to the RCT. There was consistent delivery in actual consultations compared with protocol and nurses' research experiences were enhanced over time. However, there were variations in delivery of the intervention suggesting that some patients valued and may benefit from the program, but not all patients needed this program.

We recommend designing implementation strategies that include workshops to develop knowledge, monitoring and feedback to improve consistent delivery and adherence to the protocol and enhance ownership.

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FIGURE AND TABLES LEGEND

APPENDICES (or supporting information online):

Table 1. Examples of quality of delivery and receipt of the intervention

Intervention fidelity assessment	Codes	Quotes (sampling)
Quality of delivery - Data from Workshop #6 and #9, FGD		
Delivery in general	Situation to give advice	*One patient I talked to was perhaps depressed, he was really down, and he couldn´t see any light ahead. It ended up having to advise him - many times - to go to his doctor, and he did. I ended up having a supplemental consultation the week after; just to make sure that he was going to be better. It was hard avoiding advising him. It's hard to do that differently*' (#6)
	Content	*I have discovered is how important photographs is for patients. … Where we have taken photographs in different stages (during ICU-stay), I really can see what it does to people how they can see the progression. I am quite convinced* (#6)
Quality of delivery	Variations in readiness	'*Surprisingly, we were invited into patients' private domain… and in the telephone interviews that privacy comes so easily*' (#6)
		'I think it is hard… when patients close the questions with 'yes/no'… and when I have tried to ask how are you doing? The patient answer was; I'm fine now' (#6)
		'*I think the patients are very different, and the issues they encounter and perceive as important vary too. Typically, you ask very much about these issues. It may be that patients are not very reflective at first, but I think sometimes that the conversations you have subsequently make them more reflective. There are also consultations where you try different approaches, but on the bottom line, nothing more appears. However, we shall not dig or pry'* (#6)
	Factors related to readiness	'*It takes a lot of time for patients to be ready to talk about it … Maybe it's not always at that time they can open up … It makes a difference that you can't see how patients react … it's a little harder on the phone if they keep closing… It depends on their level of reflection*' (#6)
	Reflection sheets	'*I think it may be that you are exposed to the same questions again that confronts you with the fact that you actually are getting worse. Suddenly, to reflect on that, for six months ago I was better than I am now and that may also be the resistance to answer those questions again*' (#9)
		'*Some of the questions are very close related, and they say: 'I think I have answered that question once', and you have to respect that, of course.'* (#6)
Receipt of the intervention - Data from nurse-led consultations with patients on the program		
First consultation,	Equal partners	'You decide the pace' (PN) - *Then it is the first time in my life'* (P4)

CI	Roles in the interaction	*'Now, we have to talk professionally (laughing)'* (P11) - No, I'm really interested in hearing about how you are at the moment' (PN)
	Ineffective way to get patients to narrate	*There is so much I don't remember…'*(P6) - 'From your ICU-stay?' (PN) *'No, no, in general, when I was hospitalized'* (P6) - 'You can't?' (PN) *'No, not at all…'* (P6) - 'What was your first memory, when you woke up?' (PN) *'Yes, that's the problem, I don't remember'* (P6)
	Pictures	*'On this picture, you were sleeping (looks at the details on the picture) and this was the ventilator, and the red spot on the picture was the alarm from the monitor because you started to wake up'* (PN in P3's CI)
	Mirroring	*'…But its better now'* (P1) - 'It's better?' (PN) *'Yes, it's much better, there is progress too'* (P1)
	Active listening	'You would describe your situation as live-threatening?' (PN) - *'Absolutely, after some consideration, it was quite a ride (meaning dangerous and overwhelming). But that is past now, you have to move forward'* (P2)
	Value-clarifying responses	'You had trouble with your short-term memory. Did you ask your family, if they think it's a problem too?' (PN) - *'No, I don't know'* (P5) (Asked the family present) 'What is your opinion about that?' (PN)
	Advice	*'I think it's bad that I continue losing weight'* (P4) - 'You need extra food' (PN) *'Yesterday, I discovered that I had lost 4 pounds again, and that is too much for me'* (P4) - 'You have to eat whipping cream (laughing), something with high energy in' (PN) *'yes…'*(P4)
Second and third consultation, CII and CIII	Opening	'What happened since last time we spoke together?' (PN)
		'You talked about… how is that going?' (PN) - *'This is the first time anyone from the hospital asked me that* (P6)'

	'I would like to know more about...'[§]	*I don't know because I feel I know enough'* (P10)
	Most frequently used reply	'*When you get home, then something of it, I also would have liked, we've talked about we needed a plan*' (P1) - '*At discharge?*' (PN) '*Yes, from hospital*' - '*It's a big step to come home, and nobody keeps a hold of one*' (PN) '*No, it was like a plan for rehabilitation, and we never got it… There has been too long a period of uncertainty, for example, why does it hurt here*' - '*It could have created more security?*' (PN) '*I think so. To get more knowledge that is accurate about what is okay to do of exercises. It hurts a bit here but it doesn't matter much ... I'm afraid and scared due to pain*' (P1)

PN: provider nurses, P1-P12: patients, [§]One of the 16 unfinished sentences from the reflection sheets

Table 2. Examples of PNs experiences and patient responses

Provider nurses' experiences
Individual patient benefit from intervention
- 'It has been with mixed emotions… It was my experience that most patients perceived it very positively and wanted to participate because it felt meaningful to them… there was actually someone who already really wanted consultations and when they ended up in the control group, so it could be a bit frustrating, to say to them that we can't offer you the intervention' (PN8)
- 'In fact, some believed that it was for me that they should have this consultation' (PN6)
Research beside daily practice
- 'It made it quite difficult to track them (patients). It was something of a detective job to keep an eye on them and we were glad for being a small department and only two persons managed the research, so we knew that we had reasonable control of it.' (PN11)
Learning process linked to practice and peers support
- 'The first consultation was with some nervousness, as I remember, but the more you implement, the easier it was' (PN1)
- 'What I also noticed along the implementation was that what we learned about question techniques helped me as a nurse in the department during problematic conversations' (PN2)
- 'For me, it's really a lot about attending workshops, where we've been united and gained some new knowledge to work with, the theory we've been presented, and the reflections across the group, it has been absolutely encouraging and good for us, that just keep up the spirit' (PN6)
Prerequisites for implementation
- 'The challenge was to implement research projects, which is new to nursing… it's an old culture … something that is new is not ingrained in the culture yet. I think it required a lot of project management…' (PN12)
Patient responses
Response to first consultation (CI): Helps the patient to move forward
- Thank you for today – it was helpful (P1)
- I think gradually I've got bits into place now; even if it's uncomfortable to talking about, it has to be discussed, or it never will feel natural (P3)
- Actually, I've been looking forward to talk about it, you see, to hear about some of the things that I've been through (P6)
Response to second consultation (CII): Helps the patient to understand
- It's good to know that I can always contact you, even if I don't do it after our planned follow-up consultations (P3)
- I got a lot of answers to things that I remembered; I see it more clearly now. It's been helpful (P6)
- When I saw the unit and equipment with a clear mind, I understood better although my children had explained it to me. At first, I couldn't remember anything (P11)
Response to third consultation (CIII): A necessary part of recovery
- All that was missing was that someone took care of me in this process. Nobody else has contacted me. Actually, I think this has helped me because I had to reflect on things I wouldn't have thought

about. I've had a feeling of someone caring and taking me seriously. That has been good (P1)

- I've gotten insight into many things, and values, which I didn't have before (P2)
- But it's a great advantage to have gained so much insight. The fact that you have gone out of your way to tell me what happened (P3)
- It has been really good, I was very happy when I was at the hospital the first time. I got my photographs to take home and all that (P6)
- Thank you for talking to me (P7)
- It was good, but it's also nice to know that some people do recover from such an experience (P8)
- It was a powerful experience to be far out and get back again; especially, when I've returned so well. It has been good talking to you (P11)

Figure 1. Design within Medical Research Council's (MRC) framework